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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,702	04/15/2002	Camilo Anthony Leo Selwyn Colaco	8830-24	7592

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DRINKER BIDDLE & REATH
ONE LOGAN SQUARE
18TH AND CHERRY STREETS
PHILADELPHIA, PA 19103-6996

EXAMINER	
SHAHNAN SHAH, KHATOL S	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,702	COLACO, CAMILO ANTHONY LEO SELWYN	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *1-7,12 and 13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-13* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment received 04/15/2002 is acknowledged. Claims 1-13 have been amended. Abstract of disclosure on a separate page has been submitted.

Election/Restrictions

2. Applicant's election with traverse of March 05, 2004, is acknowledged. Applicant provisionally elected Group II claims 8-11 which are drawn to a vaccine containing an immunogenic determinant in which the immunogenic determinant is one or more complexes of stress protein.

Applicant explanation that present application represents the U.S. stage of a PCT Application, as filed under 35 U.S.C. 371 has been noted. The examiner respectfully apologizes for any misunderstanding in this matter. The special technical feature of the invention as also stated by the applicant is the immunogenic determinant, which comprises one or more complexes of a heat shock or stress protein and antigenic peptide fragments derived from a stressed cell infected with an intracellular pathogen. Srivastava, P. K. teaches immunogenic determinant, which comprises one or more complexes of a heat shock or stress protein and antigenic peptide fragments derived from a stressed cell infected with an intracellular pathogen (see title, abstract and claims).

Therefore, the technical feature linking the inventions of groups I- III does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art.

The requirement is still deemed proper and is therefore made **FINAL.**

3. Currently claims 1-13 are pending.

4. Claims 1-7 and 12-13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions.

5. Currently claims 8-11 are under consideration.

Drawings

6. This application lacks formal drawings. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

Specification

7. The disclosure is objected to because of the following informalities:

The words "immunisation" and "immunised" are misspelled in the specification. Immunization is spelled with a "z" not "s". Appropriate corrections are required.

8. The use of the trademarks such as QUIL A and RPMI have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Priority

9. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or

continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 8-11 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15 of copending Application No. 10/049,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims of both applications are drawn to a vaccine composition comprising an immunogenic determinant, which comprises one or more complexes of a heat shock or stress protein and antigenic peptide fragments derived from a stressed cell infected with a pathogen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition comprising a complex of shock protein and an antigenic peptide, does not reasonably provide enablement for a vaccine. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP) 2164.01(a). Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples (6) the quantity of experimentation, (7) the relative skill of those in the art, and (8) the breadth of the claims.

In the instant case claims 8-11 are drawn to a vaccine. The examples in the specification in pages 12-18 are reciting production of heat induced stress proteins (example 1) induction of immunity, production of antibodies and cytotoxic T-cell activity (examples 2 and 3). The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity for prevention or treatment of disease. The term "vaccine" encompasses the ability of the specific antigen to induce protective immunity, in the case of the instantly claimed invention, the protection or prevention of infection would be against

pathogenic organisms (i.e. bacteria and parasites). When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated base on that limitation. See in re Vaeck, 947 F. 2d 488, 495,20 USPQ 2d 1438, 1444 (Fed Cir, 1991).

Dorland's Medical Dictionary (29th Edition, 2000) defines "vaccine" as "a suspension of attenuated or killed microorganisms (bacteria, viruses, or rickettsiae), or of antigenic proteins derived from them, administered for the prevention, amelioration, or treatment of infectious diseases. In the instant case the applicant's invention is not enabled for the prevention, amelioration, or treatment of all bacterial and parasitic diseases as broadly claimed. The specification page 15 recites induction of immunity to a pathogen was assayed on Western blot analysis using total *plasmodium* or *M.bovis*. The specification fails to specify what the vaccine was used for what was the *dosage* frequency as well as the specific identity of diseases for which the instant invention is applicable (i.e. will be effective for treating or preventing) there has not been provided adequate guidance in the specification for accomplishing and determining such. It is well known in the art that there is currently no vaccine to prevent all bacterial and parasitic infections because of a lack of good animal models for the diseases, a lack of information about the protective antigens, a lack of in vitro correlates to immunity against bacterial and parasitic disease in humans and the pathogenic mechanisms and host immune response to the pathogens has yet to be determined. In the specific disease such as Mycobacterial disease, the history of vaccination in humans against said disease is notorious for a lack of successful protection. In addition, at the time of filing of the instant specification, there remained a lack of correlation of success in animal models with successful vaccination of humans against mycobacterial disease, as evidenced by the review article,

"Evaluation of the Protective Potency of New Tuberculosis Vaccines", Review of Infectious Diseases, Vol. 11, Supplement 2, pages S484-S490, March-April 1989.

In summary, it is determined that 1) insufficient direction or guidance is presented in the specification with respect to selecting vaccines having claimed functional feature of capability of generating protective responses, 2) there are no working examples which suggest the desired results of a vaccine against intra-cellular pathogens, 3) the nature of the invention involved the complex and incompletely understood area of protective immune responses against disease, 4) the state of the prior art shows the lack of correlates to immunity with intra-cellular pathogens, 5) the relative skill of those in the art is commonly recognized as quite high (post – doctoral level), and the lack of predictability in the field to which the invention pertains is recognized in the art as evidenced by the cited prior art.

In view of all of the above, in view of the lack of predictability in the art, it is determined that it would require undue experimentation to make and use the invention commensurate in scope with the claims.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

15. Claims 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 1 is vague and indefinite in the use of the phrase " peptide fragment derived from" because it is unclear how the claimed product is undergoing any kind of chemical

modification as implied by the recitation of "derived". Therefore, there is no way for a person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

Claim 9 is referring to a method of a non-elected claim (i.e. method of claim 1). Claim 9 is indefinite as being dependent from a non-elected claim.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 8-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Srivastava (US 6,048,530).

Claims are drawn to a vaccine composition comprising an immunogenic determinant comprising one or complexes between a shock protein and an antigenic peptide from the heat stressing of a cell infected with a bacterial, protozoal or parasitic intra-cellular pathogen.

Srivastava teaches a vaccine composition comprising an immunogenic determinant comprising one or complexes between a shock protein and an antigenic peptide from the heat stressing of a cell infected with a bacterial, protozoal or parasitic intra-cellular pathogen (see title, abstract and claims). Srivastava teaches that a vaccine containing a stress protein peptide complex when isolated from cells infected with an intracellular pathogen and then administered to a mammal can effectively stimulate immune response against the pathogen (see column 4, line 60-68 summary of the invention). Srivastava teaches bacteria and protozoa (see column 7, lines

1-15). Srivastava teaches pharmaceutical carriers including aqueous composition and adjuvants (see column 23, lines 19-68). Srivastava teaches a method of producing the stress proteins including heat shock proteins and complex vaccine (see columns 5, 13 and 14). The prior art teaches the claimed invention.

Since the office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed composition and the composition of the prior art (i. e., that the composition of prior art does not possess the same material structure and functional characteristics of the claimed composition). See In re Best, 562 F.2 d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

Art Unit 1645

May 24, 2004

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER